

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

**ENDO PHARMACEUTICALS INC. and
GRÜNENTHAL GMBH,**

Plaintiffs,

v.

**AMNEAL PHARMACEUTICALS, LLC
and AMNEAL PHARMACEUTICALS OF
NEW YORK, LLC,**

Defendants.

C.A. No. 12-cv-8115-TPG-GWG

FILED UNDER SEAL

**ENDO PHARMACEUTICALS INC. and
GRÜNENTHAL GMBH,**

Plaintiffs,

v.

**TEVA PHARMACEUTICALS USA, INC.,
and BARR LABORATORIES, INC.,**

Defendants.

C.A. No. 12-cv-8060-TPG-GWG

**ENDO PHARMACEUTICALS INC. and
GRÜNENTHAL GMBH,**

Plaintiffs,

v.

**IMPAX LABORATORIES, INC. and
THORX LABORATORIES, INC.,**

Defendants.

C.A. No. 12-cv-8317-TPG-GWG

**ENDO PHARMACEUTICALS INC. and
GRÜNENTHAL GMBH,**

Plaintiffs,

v.

IMPAX LABORATORIES, INC.,

Defendants.

C.A. No. 13-cv-435-TPG-GWG

ENDO PHARMACEUTICALS INC.,

Plaintiffs,

v.

**PAR PHARMACEUTICAL COMPANIES,
INC. and PAR PHARMACEUTICAL,
INC.,**

Defendants.

C.A. No. 13-cv-3284-TPG-GWG

ENDO PHARMACEUTICALS INC.,

Plaintiffs,

v.

ROXANE LABORATORIES, INC.,

Defendants.

C.A. No. 13-cv-3288-TPG-GWG

ENDO PHARMACEUTICALS INC.,

Plaintiffs,

v.

**RANBAXY LABORATORIES LTD.,
RANBAXY INC., AND RANBAXY
PHARMACEUTICALS INC.,**

Defendants.

C.A. No. 13-cv-4343-TPG-GWG

C.A. No. 13-cv-8597-TPG-GWG

**DEFENDANTS' STATEMENT OF THE ELEMENTS AND FACTS
REGARDING
THE ON-SALE BAR UNDER 35 U.S.C. § 102(b)**

TABLE OF CONTENTS

I. Introduction.....1

II. Elements and Facts for the On-Sale Bar1



III. Conclusion4

TABLE OF AUTHORITIES

Cases

<i>August Tech. Corp. v. Camtek, Ltd.</i> , 655 F.3d 1278 (Fed. Cir. 2011)	3
<i>BarmagBarmerMaschinefabrik AG v. Murata Mach., Ltd.</i> , 731 F.2d 831 (Fed. Cir. 1984)	1
<i>Continental Plastic Containers v. Owens Brockway Plastic Prods.</i> , 141 F.3d 1073 (Fed. Cir. 1998)	3
<i>Cooper v. Goldfarb</i> , 154 F.3d 1321 (Fed. Cir. 1998)	3
<i>Estee Lauder Inc. v. L'Oreal, S.A.</i> , 129 F.3d 588 (Fed. Cir. 1997)	3, 4
<i>General Electric Co. v. United States</i> , 654 F.2d 55 (Ct. Cl. 1981)	1
<i>Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.</i> , 726 F.3d 1370 (Fed. Cir. 2013)	2
<i>In re Caveney</i> , 761 F.2d 671 (Fed. Cir. 1985)	1
<i>Pfaff v. Wells Elecs., Inc.</i> , 525 U.S. 55 (1998)	1, 3
<i>Scaltech, Inc. v. Retec/Tetra, L.L.C.</i> , 178 F.3d 1378 (Fed. Cir. 1999)	3
<i>Slip Track Sys., Inc. v. Metal-Lite, Inc.</i> , 304 F.3d 1256 (Fed. Cir. 2002)	3
<i>Sparton Corp. v. United States</i> , 399 F.3d 1321 (Fed. Cir. 2005)	3
<i>Special Devices, Inc. v. OEA, Inc.</i> , 270 F.3d 1353 (Fed. Cir. 2001)	2
<i>Tec Air, Inc. v. Denso Mfg. Michigan, Inc.</i> , 192 F.3d 1353 (Fed. Cir. 1999)	2

<i>U.S. Envtl. Prods. Inc. v. Westall</i> , 911 F.2d 713 (Fed. Cir. 1990)	2
--	---

Statutes

<i>Leahy-Smith America Invents Act</i> , Pub. L. No. 112-29, 125 Stat. 284 (2011).....	1
35 U.S.C. § 102(b)	1, 4

I. Introduction

[REDACTED]

[REDACTED] Undersection 102(b), a person is not entitled to a patent if the invention was “on sale in this country, more than one year prior to the date of application for patent in the United States.” In other words, a patentee has a one-year “grace period” to file a patent application from the time that the invention is deemed to be on sale under section 102(b). A patent claim is invalid under the on-sale bar if two conditions are met more than one year before the effective filing date: (i) the subject matter of the claim was the subject of a commercial offer for sale not for primarily experimental purposes, and (ii) the claimed invention was ready for patenting. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67-68 (1998); 35 U.S.C. § 102(b).

The on-sale bar furthers a number of policies, including: (1) “favoring prompt and widespread disclosure of new inventions to the public,” and (2) prohibiting an inventor from exploiting the exclusivity of his invention beyond the statutorily authorized period. *General Electric Co. v. United States*, 654 F.2d 55, 61 (Ct. Cl. 1981).

II. Elements and Facts for the On-Sale Bar

[REDACTED]

Whether an invention is on sale under 35 U.S.C. § 102(b) is a question of law. *BarmagBarmerMaschinefabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 836-37 (Fed. Cir. 1984). “[A] sale is a contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller.” *In re Caveney*, 761 F.2d 671,

[REDACTED]

676 (Fed. Cir. 1985). An invention is on sale under the on-sale bar if the thing bought or sold meets every limitation of the asserted claim. *See Tec Air, Inc. v. Denso Mfg. Michigan, Inc.*, 192 F.3d 1353, 1358 (Fed. Cir. 1999).

There is no “supplier exception” to the on-sale bar; the on-sale bar applies when anyone — inventor, supplier, or other third party — places the invention “on sale” before the critical date. *Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*, 726 F.3d 1370, 1375 (Fed. Cir. 2013); *see also Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001). “It is of no consequence that the ‘commercial offer for sale’ at issue in this case was made by [Plaintiff]’s own supplier and was made to [Plaintiff] itself.” *Hamilton Beach*, 726 F.3d at 1375. Moreover, “[a]n actual sale is not required for the activity to be an invalidating commercial offer for sale.” *Id.* at 1374. Rather, “[a]n attempt to sell is sufficient so long as it is sufficiently definite that another party could make a binding contract by simple acceptance.” *Id.* “Once a defendant demonstrates a *prima facie* case of on-sale . . . , the patent holder must come forward with convincing evidence to counter that showing.” *U.S. Envtl. Prods. Inc. v. Westall*, 911 F.2d 713, 716 (Fed. Cir. 1990).

[REDACTED]

- [REDACTED]
- [REDACTED]
- [REDACTED]

- [REDACTED]

- [REDACTED]

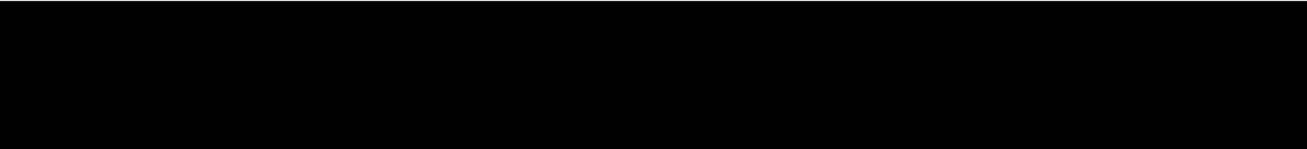
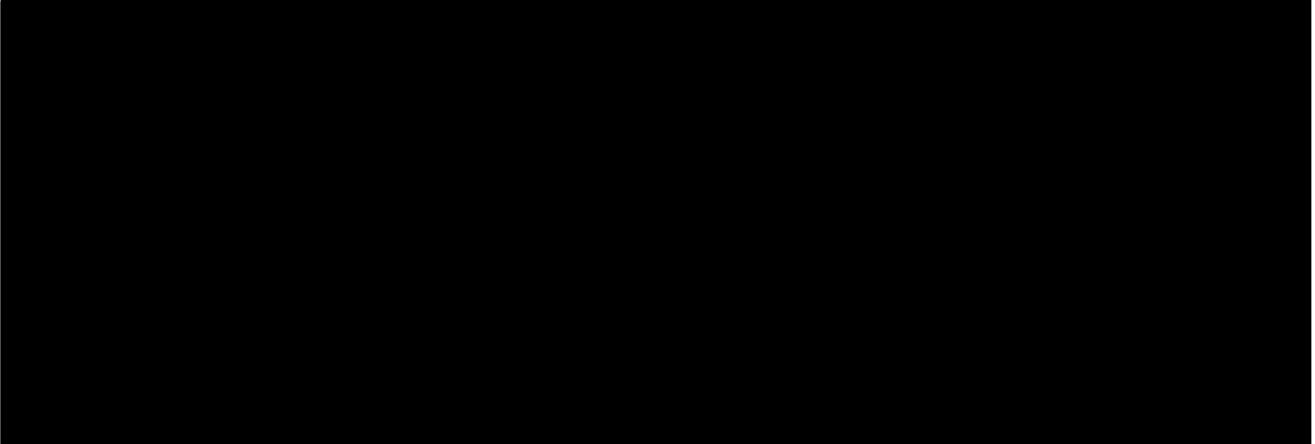
[REDACTED] See *Scaltech, Inc. v.*

Retec/Tetra, L.L.C., 178 F.3d 1378, 1384 n.1 (Fed. Cir. 1999). After an invention is reduced to practice, however, further testing will not qualify as experimental use for purposes of negating the on-sale bar. See *Continental Plastic Containers v. Owens Brockway Plastic Prods.*, 141 F.3d 1073, 1079 (Fed. Cir. 1998).



[REDACTED]

An invention is “ready for patenting” if it is enabled or reduced to practice before the critical date. *Pfaff*, 525 U.S. at 67. The “ready for patenting requirement” can be met after the offer for sale, so long as it is met before the critical date [REDACTED]. See *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1288-89 (Fed. Cir. 2011). Reduction to practice is one way an invention may satisfy the ready for patenting condition. See *Sparton Corp. v. United States*, 399 F.3d 1321, 1323 (Fed. Cir. 2005). “A composition of matter is reduced to practice when it is completely composed.” *Pfaff*, 525 U.S. at 69 n.2. To demonstrate reduction to practice, a party must prove that the inventor both (1) “constructed an embodiment or performed a process that met all the limitations [of the claim]”; and (2) “determined that the invention would work for its intended purpose.” *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). A party may prove reduction to practice through any relevant evidence, including (1) expert testimony regarding what an inventor should have known, *Slip Track Sys., Inc. v. Metal-*

Lite, Inc., 304 F.3d 1256, 1267 (Fed. Cir. 2002), (2) an inventor's knowledge of test results, *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 593 (Fed. Cir. 1997), or (3) documentary evidence demonstrating an inventor's knowledge, *id.* at 1269.



However, the “utility requirement is satisfied when an inventor has learned enough about the product to justify the conclusion that it is useful for a specific purpose.” *Estee Lauder*, 129 F.3d at 593.



III. Conclusion

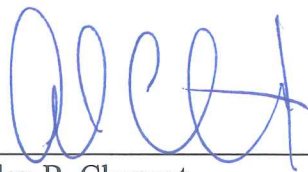


Dated: March 11, 2015



H. Keeto Sabharwal
Paul A. Ainsworth (*admitted pro hac vice*)
Uma N. Everett (*admitted pro hac vice*)
Dennies Varughese (*admitted pro hac vice*)
Rami Bardenstein
Andrew M. Nason (*admitted pro hac vice*)
Krishan Y. Thakker
Brett E. Howard
STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 New York Avenue, NW
Washington, DC 20005
Telephone No.: (202) 371-2600
Facsimile No.: (202) 371-2540
keetos@skgf.com
painsworth@skgf.com
ueverett@skgf.com
dvarughe@skgf.com
rbardenstein@skgf.com
anason@skgf.com
kthakker@skgf.com
bhoward@skgf.com


*Attorneys for Defendants Amneal
Pharmaceuticals, LLC and Amneal
Pharmaceuticals of New York, LLC*



Alan B. Clement
Paul Sudentas
LOCKE LORD LLP
3 World Financial Center
New York, NY 10281

Scott B. Feder
Keith D. Parr
Myoka Kim Goodin
Amanda K. Kelly
Wasim K. Bleibel
LOCKE LORD LLP
111 South Wacker Drive
Chicago, IL 60606

*Attorneys for Defendant Roxane Laboratories,
Inc.*



Elizabeth Holland

Huiya Wu

Daniel P. Margolis

Brian J. Robinson

GOODWIN PROCTER LLP

The New York Times Building

New York, NY 10018-1405

Tel: (212) 459-7287

Fax: (212) 355-3333

eholland@goodwinprocter.com

hwu@goodwinprocter.com

dmargolis@goodwinprocter.com

brobinson@goodwinprocter.com

Attorneys for Defendants

Teva Pharmaceuticals USA, Inc., and

Barr Laboratories, Inc.



Scott R. Samay

Anna Lamut

WINSTON & STRAWN LLP

200 Park Avenue

New York, NY 10166

(212) 294-6700

ssamay@winston.com

alamut@winston.com

Maureen L. Rurka

Kevin Warner

WINSTON & STRAWN LLP

35 West Wacker Drive

Chicago, IL 60601

(312) 558-5600

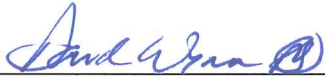
mrurka@winston.com

kwarner@winston.com

Attorneys for Defendants Impax

Laboratories, Inc. and ThoRx

Laboratories, Inc.



David N. Wynn
ARENT FOX LLP
1675 Broadway
New York, NY 10019
Tel: (212) 484-3900
wynn.david@arentfox.com

Richard J. Berman
Janine A. Carlan
Aziz Burgy
Taniel E. Anderson
Stephen Yang
ARENT FOX LLP
1717 K Street, NW
Washington, DC 20036-5342
Tel: (202) 857-6000
richard.berman@arentfox.com
janine.carlan@arentfox.com
aziz.burgy@arentfox.com
anderson.taniel@arentfox.com
stephen.yang@arentfox.com

*Attorneys for Defendants Par Pharmaceutical
Companies, Inc. and Par Pharmaceutical, Inc.*



Gregory J. Fleesler
Shari A. Alexander
MOSES & SINGER LLP
405 Lexington Avenue
New York, NY 10174-1299
(212) 554-7800
gfleesler@mosessinger.com
salexander@mosessinger.com

William R. Zimmerman
Andrea L. Cheek
**KNOBBE, MARTENS, OLSON & BEAR
LLP**
1717 Pennsylvania Avenue, Suite 900
Washington, DC 20006
(202) 640-6400
bill.zimmerman@knobbe.com
andrea.cheek@knobbe.com

Carol Pitzel Cruz
**KNOBBE, MARTENS, OLSON & BEAR
LLP**
925 Fourth Ave, Suite 2500
Seattle, WA 98104
206 405-2000
2cmp@kmob.com

*Attorneys for Defendants Ranbaxy
Laboratories, LTD., Ranbaxy Inc., and
Ranbaxy Pharmaceuticals, Inc.*

CERTIFICATE OF SERVICE

I, Shari Alexander, hereby certify that on March 11, 2015, a true and correct copy of

Defendants' Statement of the Elements and Facts Regarding the On-Sale Bar Under 35

U.S.C. § 102(b) was electronically served by email upon the following counsel:

Jonathan D. Loeb, Esq.
Jonathan.Loeb@dechert.com
Dechert LLP
2440 W. El Camino Real, Suite 700
Mountain View, CA 94040

Robert D. Rhoad, Esq.
Robert.Rhoad@dechert.com
Dechert LLP
Suite 500
902 Carnegie Center
Princeton, NJ 08540-6531

Sharon K. Gagliardi, Esq.
Sharon.Gagliardi@dechert.com
Dechert LLP
Cira Centre
2929 Arch Street
Philadelphia, PA 19104

*Attorneys for Plaintiff
Endo Pharmaceuticals Inc.*

Basil J. Lewris
Joann M. Neth
Jennifer H. Roscetti
FINNEGAN, HENDERSON,
FARRABOW, GARRETT & DUNNER
LLP
901 New York Avenue, N.W.
Washington, DC 20001
(202) 408-4000
bill.lewris@finnegan.com
joann.neth@finnegan.com
jennifer.roschetti@finnegan.com

Anthony C. Tridico
Finnegan Europe LLP
16 Old Bailey, London EC4M 7EG, United
Kingdom
anthony.tridico@finnegan.com

Attorneys for Plaintiff Grünenthal GMBH

/s/ Shari Alexander